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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,277	03/25/2004	Shen-Ping Zhong	1001.1728101	2164

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EXAMINER	
PATTERSON, MARC A	
ART UNIT	PAPER NUMBER
1772	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,277	ZHONG ET AL.	
	Examiner	Art Unit	
	Marc A. Patterson	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-17 and 19-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-17 and 19-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 102(b) rejection of Claims 3, 6 – 10, 14 – 16, 19 – 24, 27 – 37, 39 – 42 and 51 – 52 as being anticipated by Rau et al (U.S. Patent No. 6,024,722), of record on page 2 of the previous Action, is withdrawn.

2. The 35 U.S.C. 103(a) rejection of Claims 4 – 5, 11 – 13, 17, 25 – 26 and 38 as being unpatentable over Rau et al (U.S. Patent No. 6,024,722), of record on page 2 of the previous Action, is withdrawn.

3. The 35 U.S.C. 103(a) rejection of Claims 45 – 50 as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of Weissleder et al (U.S. Patent No. 5,514,379), of record on page 2 of the previous Action, is withdrawn.

NEW REJECTIONS

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3, 5 – 17, 19 – 42 and 51 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095).

With regard to Claims 3 and 6, Rau et al disclose a medical device (catheter; column 3, line 59) comprising an elongate flexible element (shaft; column 3, line 60) made from a first polymer (column 9, lines 63 – 65) comprising phenylene units (column 9, line 66) that is thermoplastic (undergoing melt flow; column 10, line 12). Rau et al fail to disclose a polymer comprising substituted 1,4 polyphenylene.

Huntjens disclose a polymer with phenylene units comprising substituted 1,4 polyphenylene in the making of articles (column 2, lines 14 – 19) for the purpose of obtaining a articles having unique physical properties over a broad temperature range (column 1, line 25). One of ordinary skill in the art would therefore have recognized the advantage of providing for the substituted 1,4 polyphenylene of Huntjens in Rau et al, which comprises a catheter, therefore an article, depending on the desired physical properties of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a polymer comprising substituted 1,4 polyphenylene in Rau et al in order to obtain articles having unique physical properties over a broad temperature range as taught by Huntjens.

With regard to Claim 5, Rau et al fail to disclose a polymer comprising benzoyl substituted 1,4 phenylene units. However, Rau et al disclose a polymer comprising phenylene units (column 9, line 66). It would therefore have been obvious for one of ordinary skill in the art

to have selected benzoyl substituted 1,4 phenylene units, as benzoyl substituted 1,4 phenylene units are among the known phenylene units.

With regard to Claims 7 – 9, the medical device is an intravascular guidewire (column 4, lines 14 – 15), therefore a core wire, which is intravascular (used in angioplasty; column 2, line 22); the core wire therefore extends from a position proximate the proximal end of the guidewire to a position proximate the distal end of the guidewire..

With regard to Claim 10, the core wire comprises a plurality of elongate longitudinally extending threads made from the polymer (parallel aligned filaments; column 9, line 5).

With regard to Claims 11 – 13, 17 – 18, 25 – 26 and 38, Rau et al fail to disclose a core wire having a circular cross sectional shape and rectangular cross sectional shape and cruciate cross sectional shape and a sleeve which is a coil and a wound flat tape and a distal varying thickness to create a first region having a first compliance and a second region having a second compliance less than the first compliance. However, Rau et al disclose a wire, therefore having an elongate shape, and a sleeve and layer, therefore having a uniform thickness. It would have been an obvious matter of design choice to have provided a circular or rectangular or cruciate cross sectional shape of the core wire and sleeve having a coil shape and a flat tape shape and distal varying thickness of the layer of Rau et al, since such a modification would have involved a mere change in shape. A change in shape is generally recognized as being within the level of ordinary skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

With regard to Claim 14, the flexible element is a sleeve extending over the wire (column 4, lines 12 – 15; Figure 1).

With regard to Claim 15, Rau et al disclose a second sleeve, disposed on the first, made from the polymer (outer layers; column 10, line 20).

With regard to Claim 16, the sleeve is an extruded tube (column 5, line 47).

With regard to Claims 19 – 24 and 27 – 28, the sleeve disclosed by Rau et al is a mesh and a weave (satin weave; column 9, line 3).

With regard to Claim 29, Rau et al disclose an inner sleeve and an outer sleeve, the flexible elongate member comprising a plurality of elongate threads disposed between the inner sleeve and the outer sleeve (the elongate member comprises a weave comprising yarn having polymeric material on its inner and outer surfaces; column 9, lines 10 – 15).

With regard to Claims 30 – 31, Rau et al disclose a blend of the first polymer and a second polymer (blend layer; column 9, line 59).

With regard to Claims 32 – 35, the medical device disclosed by Rau et al comprises a balloon (column 3, lines 60 – 66), therefore balloon sleeve.

With regard to Claims 36 – 37 and 39, the sleeves disclosed by Rau et al are extruded by any extruder (column 3, lines 55 – 57), therefore including coextrusion of the first polymer in a first layer and the second polymer in a second layer.

With regard to Claims 40 and 51, Rau et al disclose that the medical device, comprising a crosslinkable polymer, is known in the art (thermoset polyimide; column 1, line 43); Rau et al therefore disclose a second polymer which is crosslinked or is not crosslinked.

With regard to Claims 41 – 42, the balloon disclosed by Rau et al has a thickness of 1 mil (0.001 inches; column 5, lines 48 – 50).

With regard to Claim 52, the first polymer disclosed by Rau et al is a rigid rod polymer as discussed above, and is extruded as discussed above, and is therefore cooled from an extrusion process; Rau et al therefore disclose a first polymer that is crosslinked. However, the claimed aspect of the device being formed by providing the first and second polymer, followed by coextruding, followed by crosslinking the first and second polymer, is given little patentable weight as it is directed to process limitation rather than a structural limitation.

6. Claims 45 – 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Weissleder et al (U.S. Patent No. 5,514,379).

Rau et al and Huntjens disclose a medical device comprising a catheter as discussed above. With regard to Claims 45 – 50, Rau et al and Huntjens fail to disclose a catheter comprising a hydrogel coating and a therapeutic agent and a paramagnetic material comprising gadolinium III and a lubricious sheath disposed around the elongate member comprising a hydrogel polymer.

Weissleder et al teach a catheter comprising a lubricious coating (column 10, lines 35 – 40), therefore a sheath comprising a hydrogel comprising gadolinium III (column 4, lines 1 – 8) for the purpose of using a coating that is biocompatible and biodegradable (column 1, lines 10 – 14). One of ordinary skill in the art would therefore have recognized the advantage of providing for the coating of Weissleder et al in Rau et al and Huntjens, which comprises a catheter, depending on the desired biocompatibility and biodegradability of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a hydrogel coating and a therapeutic agent

and a paramagnetic material comprising gadolinium III and a lubricious sheath disposed around the elongate member comprising a hydrogel polymer in Rau et al and Huntjens in order to obtain a coating that is biocompatible and biodegradable as taught by Weissleder et al.

7. Claims 43 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rau et al (U.S. Patent No. 6,024,722) in view of Huntjens (U.S. Patent No. 3,388,095) and further in view of Lau et al (U.S. Patent No. 6,517,570 B1).

Rau et al and Huntjens disclose a medical device comprising a rigid rod polymer as discussed above. With regard to Claims 43 – 44, Rau et al and Huntjens fail to disclose a device comprising a self – expanding stent comprising a plurality of struts.

Lau et al teach a rigid rod polymer (column 13, line 5) in the making of a self – expanding stent comprising a plurality of struts for the purpose of obtaining a stent that does not shorten upon delivery (column 2, lines 13 – 30). One of ordinary skill in the art would therefore have recognized the advantage of providing for the device of Lau et al in Rau et al and Huntjens, which comprises a rigid rod polymer, depending on the desired shortening of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a device comprising a self – expanding stent comprising a plurality of struts in Rau et al and Huntjens in order to obtain a stent that does not shorten upon delivery as taught by Lau et al.

ANSWERS TO APPLICANT'S ARGUMENTS

8. Applicant's arguments regarding the 35 U.S.C. 102(b) rejection of Claim 3 as being anticipated by Rau et al (U.S. Patent No. 6,024,722), of record in the previous Action, have been considered and have been found to be persuasive. The rejections of the previous Action are therefore withdrawn.

Applicant's arguments regarding the 35 U.S.C. 102(b) rejection of Claim 51 as being anticipated by Rau et al (U.S. Patent No. 6,024,722), of record in the previous Action, have been carefully considered but have not been found to be persuasive for the reasons set forth below.

Applicant argues, on page 9 of the remarks dated October 5, 2006, that Rau et al do not disclose coextrusion.

However, as stated above, the sleeves disclosed by Rau et al are extruded by any extruder (column 3, lines 55 – 57); Rau et al therefore disclose coextrusion of the first polymer in a first layer and the second polymer in a second layer.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc Patterson 12/18/06
Marc A. Patterson, PhD.
Primary Examiner
Art Unit 1772